Guidance for a School/Institute Quality Assurance Review of Student Human Ethics Applications

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Quality Assurance and the Internal Review Rationale

The 2018 Institutional Ethics Review highlighted the need for a pre-review process at the School or Institute level to ensure the quality of all applications. This pre-review process will contribute to enhancing the quality of ethics applications submitted to the human ethics committee and reducing turnaround times. The internal reviewer is not required to perform an ethics review of applications. The purpose of their review is to ensure that the application is of an acceptable standard before it can progress to the ethics committee for review. This 'internal reviewer' would not perform an ethics review of the application but would be checking for issues such as:

- Correct review assignment;
- Scientific merit rationale and research integrity;
- Clarity including appropriate sentence construction;
- Consistency of information across all documents;
- Appropriate responses to questions;
- Adequate identification of risk and risk management within the project;
- Adherence to University and other policies; and
- Adequate oversight in the development of the application by a student's supervisor.

In addition, if the internal reviewer identifies issues within the application which they know are not in keeping with the standards of the *National Statement on Ethical Conduct in Human Research* they could flag these with the researchers for consideration prior to the finalisation of the application.

Introduction to Ethics Review – purpose, steps and rationale

Research projects conducted by University academics and students involving people, their data or their tissue are required under national and international guidelines to have the project design undergo ethical review by an independent ethics committee before the project is conducted.

In Australia this review is done under guidelines developed by the National Health and Medical Research Council (NHMRC). The key documents are the *National Statement on Ethical Conduct in Human Research, 2007 (updated 2018)* (National Statement) and the *Australian Code for the Responsible Conduct of Research*, 2018. The codes/guidelines must be used by all NHMRC registered Human Research Ethics Committees (HREC) and include the principles to be applied by ethics committees in the review and monitoring of research projects.

The purpose of ethics review is to ensure that all research conducted at Western is carried out in accordance with the guidelines, is safe, ensures that risks are well mitigated and the project is designed to respect the participants involved. At Western, the ethics committees also review for scientific integrity and research merit when this hasn't been done under a PHD CoC, MRes, PoP or Category 1 funding peer review.

Student researchers and their supervisors are encouraged to view ethics review as an opportunity to have independent input into the development of the project that will not only help ensure that research participants' rights are protected but will also improve the research design and increase the probability of a successful research outcome.

Checklist for QA Review of Student Ethics Applications

If a School/Institute internal reviewer is not appointed, the student's supervisor should use the checklist to confirm the application is ready to be submitted for ethics review.

Issue	Check for	Supporting information
Correct review assignment	Many student human ethics applications are reviewed by a Western Sydney ethics committee but some will not be, or also require, review by other ethics committees. If the internal reviewer is unsure that the researchers understand which committee they should be sending the application to, they can direct the researcher to the WSU ethics officers for advice. Because not all ethics committees accept the same documents as WSU it can be a waste of time for a researcher to develop their application on the wrong forms. Common examples are research involving: • Public health sites or use of patient data or staff; • Aboriginal and Torres Strait Islander Communities; • Defence Force - personnel or property; • The veteran community - personnel or property; • The jurisdiction of Corrective Services or Juvenile Justice agencies; and • Police Force staff or research which impacts on principles and practice of policing.	List of Human Research Ethics Committees registered with the NHMRC https://www.nhmrc.gov.au/sites/default/files/documents/attachments/registered-hrecs.pdf **In the HREA** For applications that are coming to WSU and require more than one type of review, HREA Q1.14 provides an opportunity for the researcher to identify other specialist review of the application.
Scientific merit rationale and research integrity	Section 1, page 9 of the National Statement says: *Unless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable.* Evidence of scientific merit includes: • The provision of a relevant literature review with complete citations; • A background that establishes the grounds for the research and sets the scene for the rationale/justification; • Identification of the gap in knowledge to be addressed; • Evidence the research team has the expertise to perform all aspects of the project; and • For PHD and MRes projects – evidence of completion of the CoC and PoP.	**In the HREA** Section 1 seeks information about the relevance and expertise of the research team for the project proposed. A reference to the person's CV or University position is not sufficient. Q1.12, 1.12.1 and 1.12.2 asks questions about prior scientific merit review **Project Description**

	The feasibility of the project should be considered. Some HDR students have very limited timeframes in which to complete their project and the research outcomes must be achievable within that timeframe.	Section 4 includes the literature review, aims, methods and outcomes statements. Evidence of CoC or PoP should be attached to the application.
Clarity including appropriate sentence construction	All documents should be checked for: • Adherence to the word or character count limits; • Spelling and grammatical errors; • That sentence construction does not interfere with the reader's understanding of the information; • Documents are written in plain English that can be understood by a lay person; • If scientific language is used, an explanation suitable for a non-specialist is provided; and • Information in the Participant Information Sheet and other public documents is clear, easily understood and age-appropriate (Australasian Ethics Network consensus indicates that the adult information sheet should be written to a literacy level equivalent to Year 8 High School)	
Correct documentation and consistency of information across all documents	Western Sydney requires that ethics applications include an HREA form; the WSU bespoke Project Description (unless the project is a Clinical Trial in which case documents should conform to Good Clinical Practice Guidelines); a data management plan created on the University template and other documents relevant to the project. There are WSU templates for the more commonly used documents. There should be evidence that the application and supporting documents have been thoroughly proof-read to ensure consistency across all documents. It is not uncommon for researchers to start an application for a project, make revisions to the methods or participant groups while working on the project, but then forget to revise all documents accordingly: • The project title and the named researchers must be the same across all documents; • If there is more than one participant group, then it is probable there will need to be more than one participant information sheet and consent form; • The scope of consent – specific, extended or unspecified – must be consistent across all documents and the answers in the Project Description and HREA must reflect the implications of the chosen scope of consent; and	The internal reviewer should check that all relevant supporting documents are attached and are clearly named and where necessary cross referenced in the application. Broadly this covers the: • mandatory documents noted above; • information and consent documents including the explanation of extended or unspecified consent; • data collection tools; • recruitment texts including emails asking for participation, or social media texts; • letters of support or agreement to access data from other parties; and • CoC or PoP emails of agreement from the GRS.

	• The research methodologies chosen in the Project Description and HREA must be supported by appropriate data collection tools e.g. is survey is the method a copy of the survey must be included, not a document called interview schedule.	
Appropriate responses to questions and tailoring of document templates	The information provided must be relevant to the specific question. It is sometimes evident that: • The researcher's English language skills mean they miss the nuances of the question; • The researcher has cut and pasted from another document rather than tailoring the response to the question in the form; and • The researcher has created a broad body of text that is used at many of the application answers rather than providing only the information required at each answer. The University templates must be tailored for the project. University staff and students must use Western Sydney email addresses or phone numbers.	WSU provides a number of guidance documents and web text to help researchers understand how to respond to questions. These are held at: https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics
Adequate identification of the risk and the risk management within the project	It should be evident that, in evaluating risk: • The researcher has identified and addressed risks to all parties e.g. the participants, research team and organisations; • The concept of risk has been considered in line with how risk is discussed in the National Statement. For example, even 'inconvenience' is considered a risk for participants that should be minimised; and • There is a clear explanation for how each risk will be mitigated/managed. This may include providing additional documents such as a 'home visits protocol' which will need to be developed by the researcher, and/or providing assurances that all researchers will have Working with Children checks.	**National Statement** Section 2 identifies issues associated with risk generally. Section 4 discusses issues associated with certain participant groups. **In the HREA** Q2.3.1 and Q2.3.2 are the key questions. **Project Description** Q6.14 asks for a summary of the risks for that participant group.

Adherence to University and other policies	Ethics review is one component of the overall governance requirements of human research projects. There are also University policies, sometimes School policies, and sometimes legislative frameworks that impact on the research design and 'appropriate' answers in the ethics application. These include: • School/Institute policies e.g. approval to conduct research; access to student data; claiming funds from research budgets for participant reimbursements; • WSU policies - Research Code of Practice; Data management; Intellectual property, Privacy; • State and Commonwealth Privacy legislation, particularly if a waiver of consent is required for the project; and • Legal requirements - Working with children checks; use of telecommunications devices. The internal reviewer should direct the researcher to appropriate policies if they think the application does not adequately reflect them.	WSU Policies
Adequate oversight in the development of the application by a student's supervisor	The internal review, and the ethics review, should not be expected to take the place of the supervisor in the development or review of the student project. The internal reviewer should be assured that student applications have been written with assistance from experienced academics and/or the student's supervisor. If an internal reviewer perceives the application has had minimal to no intervention or review from the supervisor, the internal reviewer should liaise with the supervisor and student, outlining the need for the supervisor to assist with the development of the application.	**In the HREA** The application must be signed by, or emails of agreement attached from, all named researchers on the application. In providing their signature or email to student projects, supervisors are confirming they have provided adequate input into the project and application development. Section 1 must have a section for each named researchers. Q1.9.11 must say 'no' which generates space for a signature in the HREA. **Project Description** Section 2 asks about School/Institute review and whether it has been done.

Steps Post Internal Review

The internal reviewer should not impose their concept of how a project should be done, or what the research question should be, but rather check that what is planned to be done is well articulated and consistently explained in the ethics application, and the project approach is supported by good research practice and adequate knowledge of the research field and methodologies.

The internal reviewer will need to decide whether the criteria noted in the application checklist have been met and it can be expected that the ethics committee will be able to understand the project and apply the considerations of ethics review as per the National Statement.

Student applications that are of poor quality should not be approved by the internal reviewer for progression to the ethics committee.

Appendix 1 outlines a workflow that internal reviewers might want to adopt. Internal reviewers may want to provide the student and supervisor with written comments to assist them with revising the application. It is up to the internal reviewer whether a second checking process then occurs.

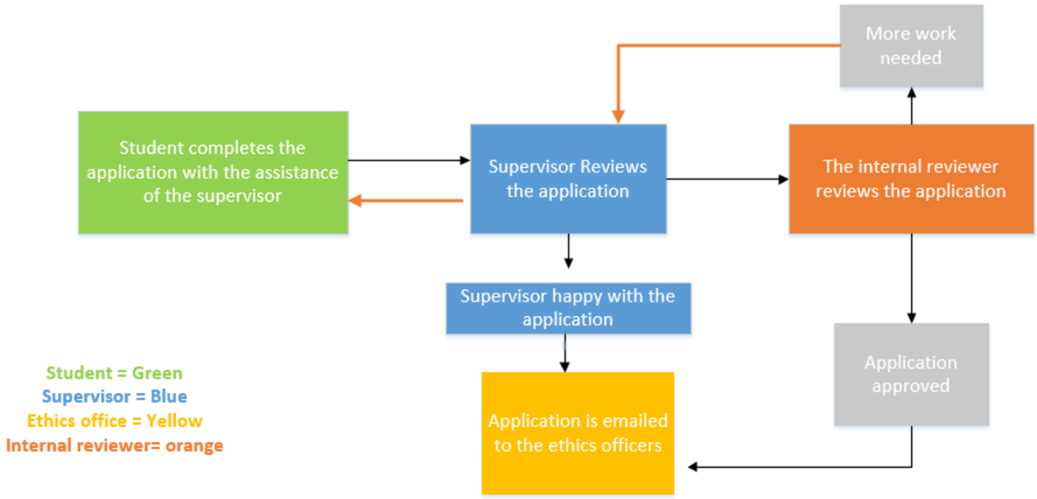
The internal reviewer might consider providing the applicant with a statement of agreement to progress to ethics review that could be sent with the ethics application.

Appendix 3 provides additional resources that the internal reviewer may want to:

- Use as part of the internal review process; and
- Share with the applicant to help them improve the ethics application.

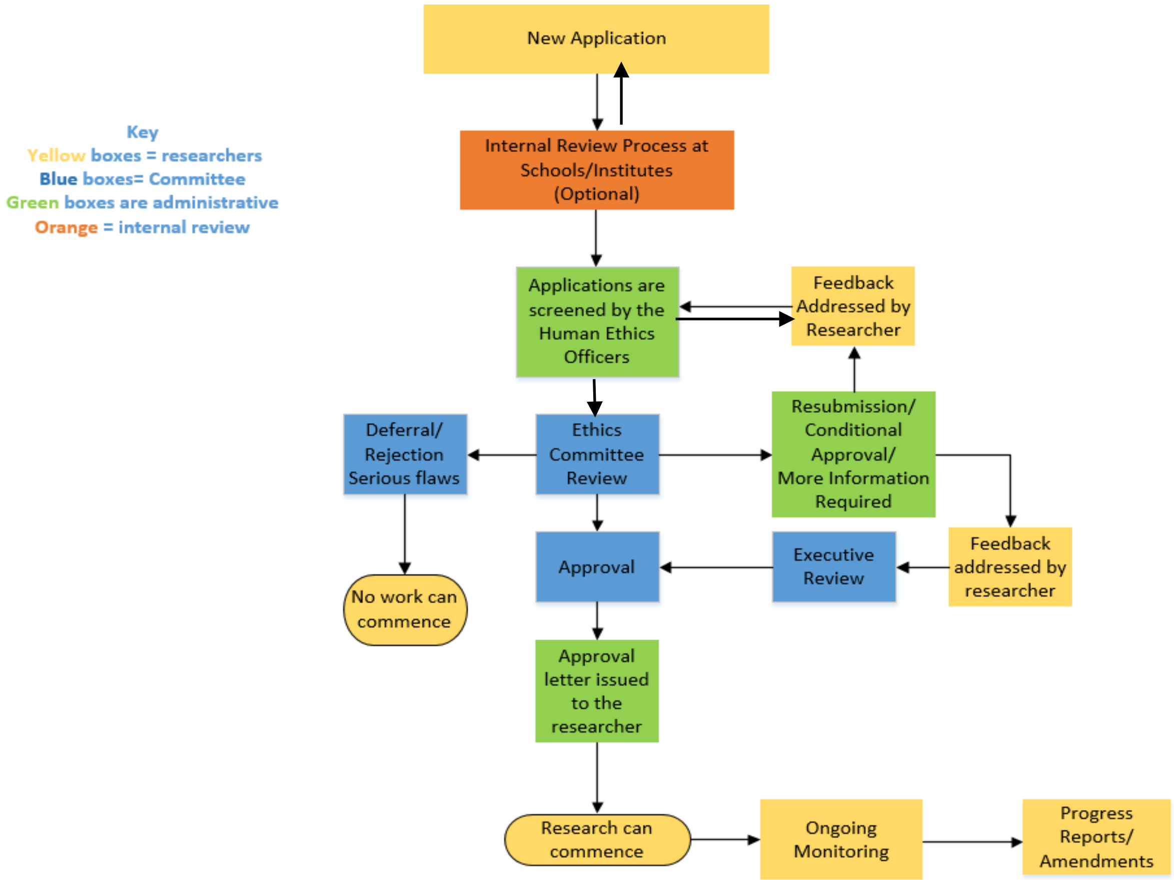
Appendix 1. Suggested steps in the internal review process

The below flowchart is an example of how the review process could take place.



Appendix 2. Steps involved in the ethics committee review process

The flowchart below illustrates the ethics committee preferred review model



Appendix 3 Useful Guidelines and Frameworks

1.NHMRC

1.1. The *National Statement on Ethical Conduct in Human Research, 2007 (updated 2018)* should be used by the internal reviewer to understand questions included in the application form for human ethics.

The *National Statement* provides guidance to researchers, HRECs and governance review bodies regarding the ethical development, implementation and evaluation of research.

Section 1 of the *National Statement* outlines the values and principles of ethical conduct including research 'merit and integrity', 'justice', 'beneficence' and 'respect'. Section 1 specifies the requirements that research projects must meet. Both the Project Description Form and the Human Research Application Form (HREA) have questions that ask researchers to demonstrate that their research has met the criteria outlined in Section 1 of the *National Statement*.

Section 2 discusses the elements of risk, benefits and consent. The internal reviewer can refer to this section, if they need guidance on completing sections of the Project Description or the HREA that relate to risks, benefits and consent.

Section 3 describes the ethical considerations relating to the design, development, review and conduct of research and Section four for the ethical considerations specific to participants.

1.2. HREA Resources including guidance and 'how to' videos. This information helps users understand the functionality of the HREA website.

https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-applications-hrea/human-research-ethics-applications-hrea-resources

1.3. NHMRC ethical issues and resources. A range of NHMRC documents relating to human participation in research.

https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources

1.4. NHMRC eLearning Modules for Clinical Trials. Referencing the principles of Good Clinical Practice.

https://www.australianclinicaltrials.gov.au/nhmrc-elearning-modules

2. Western Sydney University

2.1 The Human ethics homepage contains guidance documents on how documentation should be completed.

The Ethics Resource library holds exemplar applications for students and staff to refer to.

The Integrity Online training module.

The Human Ethics Officers consultations with students and researchers.

Library for data management and statistics sessions

Research Services can provide Associate Deans, Research (or equivalent) with a list of students who have applications logged with human ethics showing where they are in the review process i.e. approved or still under review.